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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,764	03/20/2006	Fysh Dadd	22409-00257-US	6613

30678 7590 10/23/2009

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EXAMINER	
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ART UNIT	PAPER NUMBER
3766	

MAIL DATE	DELIVERY MODE
10/23/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/539,764	DADD ET AL.	
	Examiner	Art Unit	
	JESSICA REIDEL	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 June 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,12-17,20-26 and 34-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,12,13,15-17,20-24,34,35,37-39 and 43* is/are rejected.

7)☒ Claim(s) *14,25,26,36 and 40-42* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 June 2009* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/10/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Acknowledgement is made of Applicant's amendment, which was received by the Office on June 18, 2009. Claims 5-8, 10, 11, 19, and 27-33 are newly cancelled. Claims 9 and 18 were previously cancelled. Claims 34-43 are new and have been added. Claims 1-4, 12-17, 20-26, and 34-43 are currently pending.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on September 10, 2009 has been acknowledged and is being considered by the Examiner.

Drawings

3. In view of the response filed June 18, 2009, the objections made against the drawings in the Non-Final Rejection mailed March 18, 2009 (herein the previous Office action) have been withdrawn. The replacement drawings were received and have been accepted by the Examiner.

Claim Objections

4. In view of the response filed June 18, 2009, the objections made against the claims in the previous Office action have been withdrawn.

5. Claims 14, 16, 17, and 43 are objected to because of the following informalities: inadvertent typographical and/or grammatical errors exist in these claims. For example, the recitation "said said orifice" in the last line of Claim 14 should be changed to read "said orifice" instead. Also, the recitation "said spherical member when said spherical member" in the last line of Claim 16 should be changed to read "said spherical shape or said spherical member when said sealing" instead and the recitation "said spherical member" in the last line of Claim 17 should be changed to read "said spherical shape or said spherical member" instead in order to remain consistent throughout the claim(s) and to avoid antecedent basis problems. Similarly, the recitation of "the stiffening member" in the second line of Claim 43 should be changed to read "the stiffening element". Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. In view of the response filed June 18, 2009, the rejections applied against the claims under the first and second paragraphs of 35 U.S.C. 112 at pages 4-5, paragraphs 7-12 of the previous Office action have been withdrawn.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his invention.

8. Claim 43 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Claim 43 recites the limitation "the narrowing" in the second line of the claim. Claim 43 also recites the limitation "the spherical member" in the third line of the claim. There is insufficient antecedent basis for these limitations in the claim.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the Applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the Applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by ***Sundquist et al. (U.S. 2002/0077685)*** (herein Sundquist). As to Claim 1, Sundquist expressly discloses an implantable medical electrical lead, read as an implantable tissue-stimulating device 10, comprising: a resiliently flexible elongate lead body, read as a resiliently flexible elongate member 12/200, having at least one electrode mounted thereon (see, for example, tip electrode assembly 16 and ring electrode 20 depicted in Sundquist Fig. 1A); a stiffening element such as a stiffening stylet (see, for example, stylet assembly 62 having a stylet body 64 depicted in Sundquist Fig. 1A) or stiffening guide wire (see, for example, guide wire 22 of Sundquist Fig.

1D or guide wire 400 of Sundquist Figs. 7-8); a lumen 204 extending through at least a portion of the elongate member 12/200 from an orifice in the elongate member 12/200, the lumen configured to receive the stiffening element through the orifice; and a seal 76c disposed in the lumen 204 and configured to be pierced by the stiffening element, and configured to substantially seal the lumen 204 following removal of the stiffening element from the lumen 204 (see, for example, Sundquist Figs. 1D and 2-8). See also, Sundquist in its entirety and in particular, Sundquist the Abstract, Figs. 1A, 1D, 2, 7, 8 and 10A, page 2, paragraphs 16, 18, and 19, page 3, paragraphs 43-45, pages 3-4, paragraph 50, page 4, paragraph 52, and page 4, paragraph 62 through page 5, paragraph 67.

11. As to Claim 2, Sundquist expressly discloses that the stiffening element (e.g., a stylet or guide wire) is configured to extend through at least a portion of the lumen 204 and out through a distal orifice or opening (see, for example, Sundquist Figs. 1D, 7, and 8).

12. As to Claims 3 and 4, the seal 76c of Sundquist, in at least one embodiment, comprises one or more slits 1002 and is formed of a silicone polymer (e.g., silicone rubber). See, for example, Sundquist page 4, paragraph 62 through page 5, paragraph 67.

13. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by ***Westlund et al. (U.S. 2002/0077683)*** (herein Westlund). As to Claim 1, Westlund discloses a medical lead or catheter (such as a pacemaker lead), read as an implantable tissue-stimulating device 10/300/700, comprising: a lead body, read as a resiliently flexible elongate member 11/305/702, having at least one electrode mounted thereon; a needle or guide wire, read as a stiffening element 350/770 or a stylet, also read as a stiffening element 14; a lumen 344/744 extending through at least a portion of the elongate member 11/305/702 from an orifice in the elongate member 11/305/702, the lumen 344/744 configured to receive the stiffening element 14/350/770 through the orifice (see, for example, Westlund Figs. 1, 3A, 3B, and 7); and a hemostasis mechanism 320 or seal 720 (either considered synonymous with Applicant's "seal") disposed in the lumen 344/744 and configured to be pierced by the stiffening element 14/350/770, and configured to substantially seal the lumen 344/744 following removal of the stiffening element 14/350/770 from the lumen 344/744 where the Examiner considers "pierce" synonymous with "to go through or otherwise penetrate". See Westlund in its entirety and in particular, Westlund the Abstract, Figs. Figs. 1,

3A-3D, and 4-8, page 1, paragraphs 2 and 5-7, page 1, paragraph 10 through page 2, paragraph 13, page 2, paragraphs 28 and 29, and page 2, paragraph 31 through page 4, paragraph 44.

14. As to Claim 2, with reference made in particular to Westlund Fig. 7, the stiffening element 770 is configured to extend through at least a portion of the lumen 744 and out through a proximal orifice of the device 700 (see, for example, Westlund Fig. 7 and page 3, paragraph 41 through page 4, paragraph 44).

15. As to Claims 3 and 4, Westlund expressly discloses that the seal 320/720 comprises one or more slits and is formed of a silicone polymer (see, for example, Westlund Figs. 4-6 and page 3, paragraphs 34-40).

16. Claims 12, 13, 15-17, 34, 35, and 37-39 are rejected under 35 U.S.C. 102(b) as being anticipated by ***Janke et al. (U.S. 6,240,321)*** (herein Janke). As to Claims 12, 13, 15, 16, 34, 35, and 37-39, Janke discloses a lead, read as an implantable tissue-stimulating device 10/442, comprising: a lead body, read as a resiliently flexible elongate member 11/448, having at least one electrode mounted thereon (see, for example, electrode tip assembly 24 of Janke Fig. 1); a lumen 102/444 extending through at least a portion of the elongate member 11/448 from an orifice in the elongate member 11/448; a stiffening stylet, read as a stiffening element 14/460, at least partially positioned within the lumen 102/444 and extending out of the lumen 102/444 through the orifice at least during implantation of the tissue-stimulating device 10 (see, in particular, Janke Fig. 1); and a resiliently flexible and substantially spherical plug, read as a sealing member 300/400, mounted to, and moveable with, a section of the stiffening element 14/460 within the lumen 102/444 where the stiffening element 14/460 is movable relative to the orifice of the lumen 102/444 (i.e., the proximal end orifice of the device 10/442) between a first position in which the sealing member 300/400 does not seal the lumen 102/444 and a second position in which the sealing member 300/400 substantially seals the lumen 102/444. In particular, "the first position" is synonymous with a position of the stiffening element 14/460 just before it enters the lumen 102/444 through the proximal end orifice of the device 10/442 and "the second position" is synonymous with a position of the stiffening element 14/460 after it has been advanced through the lumen 102/444 to a desired position for placing or positioning the sealing member 300/400 where it is subsequently disengaged from the sealing member 300/400

by retraction or withdrawal. See Janke in its entirety and in particular, Janke the Abstract, Figs. 1, 7, and 8, column 2, line 25 through column 3, line 17, column 4, lines 28-47, column 4, line 63 through column 5, line 8, and column 8, line 38 through column 9, line 45.

17. As to Claim 17, in addition to the arguments previously presented, since the spherical member/shape comprising the sealing member 300/400 expands to seal off the lumen 102/444, it is inherent that a spherical region of the lumen 102/444 for receiving the spherical member/shape has a diameter less than that of the spherical member/shape comprising the sealing member 300/400.

18. Claims 20-23 are rejected under 35 U.S.C. 102(e) as being anticipated by ***Kuzma et al. (U.S. 7,315,763)*** (herein Kuzma '763). Kuzma '763 expressly discloses a lead, read as an implantable tissue-stimulating device 150 comprising a resiliently flexible elongate covering/carrier, read as an elongate member 60, where the elongate member 60 comprises a proximal end 110 and a distal end 71. Elongate member 60 further comprises "an electrode array 70 that has a plurality of spaced-apart electrode contacts", read as electrodes 200, and a stylet insertion channel, read as a lumen 40, extending through at least a portion of the elongate member 60 from an opening/orifice 50 positioned relatively closer to the proximal end 110 than the distal end 71. Kuzma '763 further discloses that the lumen 40 receives an insertion stylet, read as a stiffening element 77, through the opening/orifice 50 and that the device 150 further comprises an overmold, read as a seal/sealing member 75, that is pierceable by the stiffening element 77 and that is compliant and/or at least partially self-sealing such that the seal/sealing member 75 substantially seals the lumen 40 following removal of the stiffening element 77 from the lumen 40 (see, for example, Kuzma '763 Figs. 1, 3B, 4 and 5, column 3, line 55 through column 4, line 5, column 4, line 34 through column 5, line 4, column 9, line 35 through column 10, line 20, column 11, lines 53-62, and column 12, line 45 through column 13, line 52). The device 150 of Kuzma '763 further comprises a malleable ring, read as a compression member 43, mountable around at least a portion of the elongate member 60 (see, in particular, tubing end 51) where the compression member 43 is adjustable between a first, non-crushed configuration in which the compression member 43 does not compress a portion of the lumen 40 and a second, crushed configuration in which the compression member does compress at least a portion of the

lumen 40 (see, for example, Kuzma '763 Fig. 7B, column 5, lines 14-18 and column 14, lines 22-29).

Claim Rejections - 35 USC § 103

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

20. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the Examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the Examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

21. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kuzma '763. Kuzma '763 does not disclose expressly that the compression member 43 comprise a clip where upon closing and latching of the clip, at least a portion of the lumen 40 is compressed sufficiently to at least substantially seal the lumen. Instead, as previously discussed, compression member 43 comprises a malleable ring, mountable around at least a portion of the elongate member 60 (see, in particular, tubing end 51) where the compression member 43 is adjustable between a first, non-crushed configuration in which the compression member 43 does not compress a portion of the lumen 40 and a second, crushed configuration in which the compression member does compress at least a portion of the lumen 40 (see, for example, Kuzma '763 Fig. 7B, column 5, lines 14-18 and column 14, lines 22-29).

22. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the compression member 43 of Kuzma '763 such that it comprises a clip where upon closing and latching of the clip, at least a portion of

the lumen 40 is compressed sufficiently to at least substantially seal the lumen 40, because Applicant has not disclosed that a compression member comprising such a clip provides an advantage, is used for a particular purpose, or that a compression member comprising such a clip solves a stated problem. One of ordinary skill in the art, furthermore, would have expected the compression member 43 of Kuzma '763, and Applicant's invention, to perform equally well with either the compression member 43 comprising a malleable ring taught by Kuzma '763 or the claimed compression member comprising a clip because both compression members would perform the same function of compressing at least a portion of the lumen 40 to at least substantially seal the lumen 40 equally well. Therefore, it would have been *prima facie* obvious to modify Kuzma '763 to obtain the invention as specified in Claim 24 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Kuzma '763.

Allowable Subject Matter

23. Claims 14, 25, 26, 26, 40, and 41 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

24. Claim 43 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Response to Arguments

25. Applicant's arguments filed June 18, 2009 with respect to Claims 1-4, and 12-17 have been considered but are moot in view of the new ground(s) of rejection.

26. Applicant's arguments filed June 18, 2009 with respect to Claims 20-23 have been fully considered but they are not persuasive. Applicant argues that Kuzma '763 fails to disclose a compression member adjustable to a second configuration in which the compression member compresses at least a first portion of the device lumen (see, for example, pages 15-16 of the Remarks). The Examiner respectfully disagrees. Tubing end 51 of the Kuzma '763 device includes the end of lumen 40 and is compressed by the malleable ring /compression member 43

when ring/member 43 is crimped or crushed and thusly, tubing end 51 is considered synonymous with Applicant's claimed "first portion" (see, for example, Kuzma '763 Fig. 7B, column 5, lines 14-18 and column 14, lines 22-29).

Conclusion

27. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure.

28. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

29. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to JESSICA REIDEL whose telephone number is (571)272-2129. The Examiner can normally be reached on Monday - Friday, 8:00 AM - 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Carl H. Layno can be reached on (571)272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jessica L. Reidel/
Patent Examiner, Art Unit 3766
October 15, 2009

/Carl H. Layno/
Supervisory Patent Examiner, Art Unit 3766